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INSTITUTIONAL RESEARCH

Healthcare and Technology

INDUSTRY NOTE

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Arrowhead Pharmaceuticals, Inc.
(ARWR/NASDAQ/$7.16/Not rated)

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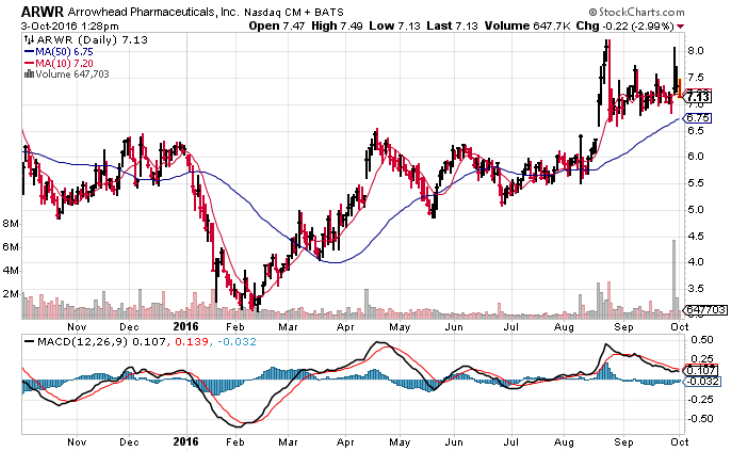
Arrowhead RNAi Deal with Amgen, Focus on Nucleotide-based Therapy Positive for Springbank Pharmaceuticals (SBPH/NASDAQ/$11.84/Not rated)

Arrowhead Pharmaceuticals and Amgen (AMGN/NASDAQ/$167.10/Not rated) announced on September 29th what we believe could become a landmark collaboration with the marrying of nucleotide-based technology with what has been historically a small molecule treated chronic disease. It was not all that many years ago that anything related to genes, i.e. DNA, RNA and other nucleotide-based technologies, was met with a "slammed door" attitude by pharma, primarily because of highly variable efficacy, a propensity for off-targeting related toxicities unpredicted by preclinical animal studies and product instability. Not anymore. In a trend gathering steam over the last year or so, top tier biotechs such as Amgen have been aggressively partnering gene and nucleotide-related technologies while moving further away from traditional recombinant protein and small molecule product development.



We expect this deal and others similar to it will drive lively pharma M&A and corporate collaboration activity for the foreseeable future, especially with early stage biotech who own nucleotide-oriented assets and technologies. Pharma and big biotech discovery and development teams are more fully embracing gene-based technologies as a novel means by which to reach better defined and stratified patient bases. The surprisingly rapid progression to the clinic and very early successes with CAR-T and CRISPR/Cas 9 (both gene manipulation) technologies started this trend, but with the ARWR/AMGN and other recent deal announcements, we see pharma's interest in nucleic acid-based therapeutics expanding.

Please find Important Disclosures beginning on Page 4.

From a strategic point of view, this type of transaction could have positive impact for Springbank Pharmaceuticals going forward. While Arrowhead is one of the few companies driving 2nd generation RNAi, Springbank remains unique in our view, with their 3rd generation platform technology of orally available short sequence nucleotide-like hybrids which may be able to supplant early generation nucleic-acid based strategies in some indications. In a broad sense, Springbank's nucleotide hybrids' in situ/intracellular "downstream" modulation may effectively side-step some efficacy and targeting issues generally related to DNA and RNA-based therapies. Just last week at the Oligonucleotide Therapy Society meeting held in Montreal, Alynlam (ALNY/NASDAQ/$66.79/Not Rated) reported discontinuing clinical development of its lead Phase I/II alpha-1 antitrypsin (AAT) candidate and moving to a second candidate because of elevated liver transaminase in higher dosed patients, likely due to off-target sequencing issues.

In the press release with Amgen, Arrowhead announced it had secured two worldwide exclusive license and collaboration agreements from Amgen to develop and commercialize RNAi therapies for cardiovascular disease utilizing ARWR's proprietary sub-cutaneous delivery RNAi platform. Arrowhead's RNAi ARC-LPA platform employs RNAi to target and reduce the production of apolipoprotein(a) or Lp(a), in order to lower elevated lipoprotein. Elevated Lp(a) is a validated genetically-defined risk factor for premature atherosclerotic cardiovascular (CV) disease that is independent of lifestyle factors and cholesterol levels. In one of the two agreements, Amgen receives a worldwide, exclusive license to the RNAi ARC-LPA platform for the atherosclerotic CV indication. The second agreement is an option to license, also on a worldwide exclusive basis, a second genetically-validated CV target. Total consideration for the two cardiovascular collaborations comprising the Agreement would exceed a peak value of $673.5 million, if all development, commercialization and sales milestones are achieved on the first license and the single digits sales royalties were achieved on the undisclosed target. Arrowhead is to receive a $35 million in cash and $21.5 million in equity at $7.16 per share as the upfront payment. Amgen will be wholly responsible for funding & conducting all of the development and commercialization activities. In short, this is a very substantial transaction.

There are a few points to be made about this particular collaboration. At the top, we believe it could be important for setting a stage by which nucleotide technologies as a whole migrate into a broader set of medical indications, including chronic diseases. As such we believe this transaction may have particular relevance to Springbank because the unique mechanism of action of their nucleotide hybrids may circumvent what may become persistent issues in other direct nucleotide-based therapeutics as these technologies are ported to an expanding range of indications. Our "take-away" points from ARWR's conference call:

1. ARWR has taken its organ-directed delivery technology from infectious disease and broadened its scope as a validated platform, now being ported to another broad disease category. Springbank may have a similar opportunity to exploit the innate immuno-modulatory nature of its nucleotide technology and compound library to establish a broader beachhead indication by a similar means.

2. ARWR successfully "flipped" a relatively recently acquired asset by quickly solving a fundamental issue: delivery. ARWR paid Novartis (NVS/NYSE/$78.87/Not rated) $10MM in cash and $25 million in stock in March 2015 for the purchase of all of its RNAi programs and assets, originally derived from Alynlam, which included the Lp(a) target. The Novartis RNAi asset purchase covered a number of gene targets but excluded delivery systems. In the conference call related to the deal announcement, ARWR management stated that once the Novartis assets were in hand, the Company put together an RNAi team from scratch (i.e., brought entirely new eyes to the problem) to build a library of RNA chemistries and structures from the aggregate of the acquired assets and exploit the internally developed novel liver-dependent delivery system. We view the increased visibility of pharma's interest in nucleotide-based therapeutics that solve particular technical issues as a significant positive for companies who have novel technologies such as is being developed by Springbank.

3. Delivery with very high specificity to a target tissue site (or cell) mattered (at this point in time) ahead of proof-of-concept in man. In this particular case, AMGN is banking on ARWR's RNAi liver-dependent technology providing the means to treat a very defined patient base for whom there is no good way to reduce circulating levels of Lp(a), because the protein is primarily expressed in the liver. To date, numerous nutritional (niacin), small molecules and peptides have been unsuccessful in the clinic, including several under development by AMGN. ARWR management noted the importance of this deal's validation of their RNAi targeted delivery platform and the fact that Amgen had been "kept in the loop" over the past several quarters as to its progress. The collaboration was struck even though the technology is still in very early stage preclinical activities and no IND-enabling studies have yet been conducted. Without IND-enabling studies in hand, we hypothesize AMGN saw convincing data demonstrating ARWR's RNAi-ARC-LPA off-targeting was low and that sufficient RNAi activity was occurring in the liver to suggest appropriate efficacy.

Bottom line: While Springbank's nucleotide hybrids technology is not being developed to specifically compete with RNAi, at the 30,000 foot level, we can foresee similar technical problems emerging with nucleic acid-based therapeutics being developed for immunotherapy and oncology applications. Already in CAR-T and CRISPR/Cas 9, precision control over gene activity across a multitude of biological processes is becoming a significant challenge resulting in the need to engineer increasingly complex systems. The ARWR/AMGN agreement suggests the door (and need) is now wide "open" to a wide variety nucleic acid technical approaches that can address the specific needs of targeted indications. *SG*

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